

**WHAT IS CLAIMED IS:**

1. A method of invoking an immune response comprising administering an insect cell composition to an organism.

2. The method of claim 1, wherein said insect cell composition further comprises an immunomodulator.

3. The method of claim 2 wherein said immunomodulator is IFN $\beta$

4. The method of claim 2 wherein said immunomodulator is IL-2.

5. The method of claim 2 wherein said immunomodulator is IL-7

6. The method of claim 2 wherein said immunomodulator is IL-15.

7. The method of claim 2 wherein said immunomodulator is IL-16.

8. The method of claim 2 wherein said immunomodulator is GM-CSF.

9. The method of claim 1, wherein said immune response is an antigen specific response.

10. The method of claim 9, wherein said antigen is a tumor antigen.

11. The method of claim 1, wherein said insect cell composition comprises cells transformed with exogenous DNA.

12. The method of claim 11, wherein said exogenous DNA is a baculovirus expression vector.

13. The method of claim 12, wherein said baculovirus expression vector further comprises an exogenous construct.

14. The method of claim 13, wherein said exogenous construct encodes an immunomodulator.

15. The method of claim 14, wherein said immunomodulator is interferon  $\beta$ .

16. The method of claim 13, wherein said exogenous construct encodes a tumor antigen.

17. The method of claim 16, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

18. The method of claim 13, wherein said exogenous construct encodes a foreign antigen.

19. The method of claim 18, wherein said foreign antigen is a pathogen specific antigen.

20. The method of claim 1, wherein said cell composition comprises *Spodoptera* or *Trichoplusia* cells.

21. The method of claim 1, wherein said cell composition comprises *Spodoptera frugiperda* cells.

22. The method of claim 1, wherein said cell composition comprises *Trichoplusia ni* cells.

23. The method of claim 1, wherein said organism is a mammal.

24. The method of claim 1, wherein said mammal is a human.

25. The method of claim 1, wherein said organism has a tumor.

26. The method of claim 25, wherein said cell composition is directly injected into said tumor.

27. The method of claim 26, comprising at least two administrations of said composition.

28. The method of claim 26 comprising at least three administrations of said composition.

29. The method of claim 25, wherein said insect cell composition comprises between about  $10^5$  and about  $10^7$  insect cells.

30. The method of claim 1, wherein said cell composition comprises intact.

31. The method of claim 1, wherein said cell composition comprises disrupted.

32. The method of claim 1, wherein said cell composition comprises lyophilized.

33. The method of claim 1, wherein said cell composition comprises freeze/thawed.

34. A method of treating a mammal having a tumor, comprising administering to said mammal a therapeutically effective amount of a pharmaceutical composition comprising an insect cell composition.

35. The method of claim 34, wherein said insect cell composition further comprises an immunomodulator.

36. The method of claim 35 wherein said immunomodulator is IFN $\beta$

37. The method of claim 35 wherein said immunomodulator is IL-2.

38. The method of claim 34, in which said composition comprises cells transformed with exogenous DNA.
39. The method of claim 38, wherein said exogenous DNA is a baculovirus expression vector.
40. The method of claim 39, wherein said baculovirus expression vector further comprises an exogenous construct.
41. The method of claim 40, wherein said exogenous construct encodes a cytokine.
42. The method of claim 41, wherein said cytokine is interferon  $\beta$ .
43. The method of claim 40, wherein said exogenous construct encodes a tumor antigen.
44. The method of claim 43, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.
45. The method of claim 40, wherein said exogenous construct encodes a foreign antigen.
46. The method of claim 45, wherein said foreign antigen is a pathogen specific antigen.
47. A method of treating metastatic tumor cells in an organism comprising administering to said mammal a therapeutically effective amount of a pharmaceutical composition comprising an insect cell composition wherein said composition activates an immune response against said metastatic tumor cells.

48. The method of claim 47, wherein said insect cell composition further comprises an immunomodulator.

49. The method of claim 48, wherein said immunomodulator is IFN $\beta$

50. The method of claim 48, wherein said immunomodulator is IL-2.

51. The method of claim 47, wherein said insect cells are transformed with exogenous DNA.

52. The method of claim 51, wherein said exogenous DNA is a baculovirus expression vector.

53. The method of claim 52, wherein said baculovirus expression vector further comprises an exogenous construct.

54. The method of claim 53, wherein said exogenous construct encodes an immunomodulator.

55. The method of claim 54, wherein said immunomodulator is interferon  $\beta$ .

56. The method of claim 53, wherein said exogenous construct encodes a tumor antigen.

57. The method of claim 56, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

58. The method of claim 53, wherein said exogenous construct encodes a foreign antigen.

59. The method of claim 58, wherein said foreign antigen is a pathogen specific antigen.

60. A method of treating a mammal having a disease state comprising administering to said mammal a therapeutically effective amount of a pharmaceutical composition comprising an insect cell composition, wherein said administering step activates an immune response against said disease state.

61. The method of claim 60, wherein said insect cell composition further comprises an immunomodulator.

62. The method of claim 61 wherein said immunomodulator is IFN $\beta$

63. The method of claim 61 wherein said immunomodulator is IL-2.

64. The method of claim 60, wherein said insect cells are transformed with exogenous DNA.

65. The method of claim 64, wherein said exogenous DNA is a baculovirus expression vector.

66. The method of claim 65, wherein said baculovirus expression vector further comprises an exogenous construct.

67. The method of claim 66, wherein said exogenous construct encodes an immunomodulator.

68. The method of claim 67, wherein said immunomodulator is interferon  $\beta$ .

69. The method of claim 66, wherein said exogenous construct encodes a tumor antigen.

70. The method of claim 69, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin

core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

71. The method of claim 66, wherein said exogenous construct encodes a foreign antigen.

72. The method of claim 71, wherein said foreign antigen is a pathogen specific antigen.

73. A kit comprising:

- a) a pharmaceutical composition, comprising an insect cell composition for the induction of an immune response and
- b) a container for said composition.

74. The method of claim 73, wherein said insect cell composition further comprises an immunomodulator.

75. The method of claim 74 wherein said immunomodulator is IFN $\beta$

76. The method of claim 74 wherein said immunomodulator is IL-2.

77. The method of claim 1, wherein said insect cells are inactivated prior to said administering step.

78. The method of claim 57, wherein said inactivation occurs by subjecting said cells to freeze-thaw cycles.

79. A vaccine composition comprising

- a) an antigenic compound;
- b) an insect cell composition; and
- c) a pharmaceutically acceptable carrier.

- 5
80. The method of claim 79, wherein said insect cell composition further comprises an immunomodulator.
81. The method of claim 80 wherein said immunomodulator is IFN $\beta$
82. The method of claim 80 wherein said immunomodulator is IL-2.
- 10
83. The composition of claim 79, wherein said insect cells are transformed with exogenous DNA.
84. The composition of claim 83, wherein said exogenous DNA is a baculovirus expression vector.
- 15
85. The composition of claim 84, wherein said baculovirus expression vector further comprises an exogenous construct.
86. The composition of claim 85, wherein said exogenous construct encodes an immunomodulator.
- 20
87. The composition of claim 86, wherein said immunomodulator is interferon  $\beta$ .
88. The composition of claim 85, wherein said exogenous construct encodes a tumor antigen.
- 25
89. The composition of claim 88, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.
- 30
90. The composition of claim 85, wherein said exogenous construct encodes a foreign antigen.



91. The composition of claim 90, wherein said foreign antigen is a pathogen specific
92. A method of establishing immunological memory comprising providing a host organism  
a pharmaceutical composition comprising an antigenic compound and an insect cell  
composition.
93. The method of claim 92, wherein said insect cell composition further comprises an  
immunomodulator.
94. The method of claim 93 wherein said immunomodulator is IFN $\beta$
95. The method of claim 93 wherein said immunomodulator is IL-2.
96. The method of claim 92, wherein said insect cells are transformed with exogenous DNA.
97. The method of claim 96, wherein said exogenous DNA is a baculovirus expression  
vector.
98. The method of claim 97, wherein said baculovirus expression vector further comprises an  
exogenous construct.
99. The method of claim 98, wherein said exogenous construct encodes an  
immunomodulator.
100. The method of claim 99, wherein said immunomodulator is interferon  $\beta$ .
101. The method of claim 98, wherein said exogenous construct encodes a tumor antigen.
102. The method of claim 100, wherein said tumor antigen is selected from the group  
consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk

mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

103. The method of claim 98, wherein said exogenous construct encodes a foreign antigen.

104. The method of claim 103, wherein said foreign antigen is a pathogen specific antigen.

105. A method of recruiting immune cells to a specific site in a host comprising, administering to said host a therapeutically effective amount of a pharmaceutical composition comprising an insect cell composition.

106. The method of claim 105, wherein said insect cell composition further comprises an immunomodulator.

107. The method of claim 106 wherein said immunomodulator is IFN $\beta$

108. The method of claim 106 wherein said immunomodulator is IL-2.

109. The method of claim 105, wherein said insect cells are transformed with exogenous DNA.

110. The method of claim 109, wherein said exogenous DNA is a baculovirus expression vector.

111. The method of claim 110, wherein said baculovirus expression vector further comprises an exogenous construct.

112. The method of claim 111, wherein said exogenous construct encodes an immunomodulator.

25036935.1

113. The method of claim 112, wherein said immunomodulator is interferon  $\beta$ .

114. The method of claim 111, wherein said exogenous construct encodes a tumor antigen.

5 115. The method of claim 114, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

10 116. The method of claim 111, wherein said exogenous construct encodes a foreign antigen.

117. The method of claim 116, wherein said foreign antigen is a pathogen specific antigen.

15 118. A method of stimulating immune cells comprising contacting said cells with an insect cell composition.

119. The method of claim 118, wherein said insect cell composition further comprises an immunomodulator.

20 120. The method of claim 119, wherein said immunomodulator is IFN $\beta$

121. The method of claim 119, wherein said immunomodulator is IL-2.

25 122. The method of claim 118, wherein said cells are stimulated *in vivo*.

123. The method of claim 118, wherein said cells are stimulated *in vitro*.

30 124. The method of claim 90, wherein said insect cells are transformed with exogenous DNA.

125. The method of claim 118, wherein said exogenous DNA is a baculovirus expression vector.

126. The method of claim 125, wherein said baculovirus expression vector further comprises an exogenous construct.

127. The method of claim 126, wherein said exogenous construct encodes an immunomodulator.

128. The method of claim 127, wherein said immunomodulator is interferon  $\beta$ .

129. The method of claim 126, wherein said exogenous construct encodes a tumor antigen.

130. The method of claim 129, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

131. The method of claim 126, wherein said exogenous construct encodes a foreign antigen.

132. The method of claim 131, wherein said foreign antigen is a pathogen specific antigen.

133. A method of treating cancer comprising:

- a) isolating cancer cells from a host;
- b) rendering said cancer cells inactive;
- c) reintroducing said inactivated cancer cells into said host in a pharmaceutical composition said pharmaceutical composition further comprising an insect cell composition.

134. The method of claim 133, wherein said insect cell composition further comprises an immunomodulator.

135. The method of claim 133, wherein said immunomodulator is IFN $\beta$

136. The method of claim 133, wherein said immunomodulator is IL-2.

5

137. The method of claim 133, wherein said cancer is localized.

138. The method of claim 133, wherein said cancer is diffuse.

10 139. The method of claim 133, wherein said exogenous DNA is a baculovirus expression vector.

140. The method of claim 139, wherein said baculovirus expression vector further comprises an exogenous construct.

15

141. The method of claim 140, wherein said exogenous construct encodes an immunomodulator.

142. The method of claim 141, wherein said immunomodulator is interferon  $\beta$ .

20

143. The method of claim 140, wherein said exogenous construct encodes a tumor antigen.

144. The method of claim 143, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

25

145. A method of treating cancer comprising:

- a) isolating cancer cells from a host;
- b) rendering said cancer cells inactive;
- c) isolating immune cells from said host;

30

- d) contacting said immune cells with a composition comprising said inactive cancer cells and said composition further comprising an insect cell composition;
- e) administering to said host a pharmaceutical composition comprising said immune cells.

5

146. The method of claim 145, wherein said insect cell composition further comprises an immunomodulator.

147. The method of claim 146, wherein said immunomodulator is IFN $\beta$

10

148. The method of claim 146, wherein said immunomodulator is IL-2.

149. The method of claim 145, wherein said pharmaceutical composition further comprises inactive cancer cells and said composition further comprises an insect cell composition.

15

150. The method of claim 145, wherein said cancer is localized.

151. The method of claim 145, wherein said cancer is diffuse.

20

152. The method of claim 145, wherein said insect cells further comprises exogenous DNA.

153. The method of claim 152, wherein said exogenous DNA is a baculovirus expression vector.

25

154. The method of claim 153, wherein said baculovirus expression vector further comprises an exogenous construct.

155. The method of claim 154, wherein said exogenous construct encodes an immunomodulator.

30

156. The method of claim 155, wherein said immunomodulator is interferon  $\beta$ .

157. The method of claim 154, wherein said exogenous construct encodes a tumor antigen.

158. The method of claim 157, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

159. A method of inducing an antitumor immune response, comprising administering to a host a pharmaceutical composition comprising an insect cell composition, wherein said pharmaceutical composition further comprises a tumor antigen.

160. The method of claim 159, wherein said insect cell composition further comprises an immunomodulator.

161. The method of claim 160, wherein said immunomodulator is IFN $\beta$

162. The method of claim 160, wherein said immunomodulator is IL-2.

163. The method of claim 159, wherein said insect cells further comprise exogenous DNA.

164. The method of claim 163, wherein said exogenous DNA is a baculovirus expression vector.

165. The method of claim 164, wherein said baculovirus expression vector further comprises an exogenous construct.

166. The method of claim 165 wherein said exogenous construct encodes a cytokine.

167. The method of claim 166, wherein said cytokine is interferon  $\beta$ .

168. The method of claim 165, wherein said exogenous construct encodes a tumor antigen.

169. The method of claim 168, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk  
5 mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

170. A method of inducing an immune response comprising;

- a) isolating immune cells from a host;
- 10 b) contacting said cultured cells with an insect cell composition, wherein said insect cells have been transformed with a baculovirus expression system wherein said baculovirus expression system further comprises an antigen gene; and
- c) reintroducing said immune cells into said host .

15 171. The method of claim 170, wherein said insect cell composition further comprises an immunomodulator.

172. The method of claim 171, wherein said immunomodulator is IFN $\beta$

20 173. The method of claim 171, wherein said immunomodulator is IL-2.

174. A method of treating cancer comprising administering to a host organism a composition comprising insect cells, wherein said organism further receives an additional anti-cancer  
25 therapy.

175. The method of claim 174, wherein said insect cell composition further comprises an immunomodulator.

176. The method of claim 175, wherein said immunomodulator is IFN $\beta$

30 177. The method of claim 175, wherein said immunomodulator is IL-2.



178. A method of preparing a vaccine comprising combining an insect cell composition with at least one antigen, wherein said combination further comprises a pharmaceutically acceptable composition.

5

179. The method of claim 178, wherein said insect cell composition further comprises an immunomodulator.

180. The method of claim 179, wherein said immunomodulator is IFN $\beta$

10

181. The method of claim 179, wherein said immunomodulator is IL-2.

182. The method of claim 178 wherein said antigen is a tumor antigen.

15

183. The method of claim 178 wherein said insect cell composition comprises cells transformed with exogenous DNA.

184. The method of claim 183, wherein said exogenous DNA is a baculovirus expression vector.

20

185. The method of claim 184, wherein said baculovirus expression vector further comprises an exogenous construct.

186. The method of claim 185, wherein said exogenous construct encodes an immunomodulator.

25

187. The method of claim 186, wherein said immunomodulator is interferon  $\beta$ .

188. The method of claim 185, wherein said exogenous construct encodes a tumor antigen.

30

189. The method of claim 188, wherein said tumor antigen is selected from the group consisting of MAGE-1, MAGE-3, Melan-A, P198, P1A, gp100, TAG-72, p185<sup>HER2</sup>, milk mucin core protein, carcinoembryonic antigen (CEA), P91A, p53, p21<sup>ras</sup>, P210, BTA and tyrosinase.

5

190. The method of claim 185, wherein said exogenous construct encodes a foreign antigen.

191. The method of claim 190, wherein said foreign antigen is a pathogen specific antigen.

10

192. The method of claim 178 wherein said cell composition comprises *Spodoptera* or *Trichoplusia* cells.

193. The method of claim 178, wherein said cell composition comprises *Spodoptera frugiperda* cells.

15

194. The method of claim 178, wherein said cell composition comprises *Trichoplusia ni* cells.